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PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

ROBERT DUNPHY,
Plaintiff,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE LLC,
Defendants.

) MDL Docket No. 1699

) CASE NO. 3:07-cv-02722-CRB

) **PFIZER INC., PHARMACIA
CORPORATION, AND G.D.
SEARLE, LLC'S ANSWER TO
COMPLAINT**

) **JURY DEMAND ENDORSED
HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as
 2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
 3 ("Searle") (collectively "Defendants"), and file this Answer to Plaintiff's Complaint
 4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
 8 Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.
 9 Defendants may seek leave to amend this Answer when discovery reveals the specific time
 10 periods in which Plaintiff was prescribed and used Bextra®.

11 **II.**

12 **ANSWER**

13 **Response to Allegations Regarding Parties**

14 1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but
 15 deny that Plaintiff is entitled to any relief or damages. Defendants admit that, during certain
 16 periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States
 17 to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
 18 accordance with their approval by the FDA. Defendants admit that, during certain periods of
 19 time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed,
 20 co-promoted and distributed Bextra® in the United States to be prescribed by healthcare
 21 providers who are by law authorized to prescribe drugs in accordance with their approval by the
 22 FDA. Defendants state that Bextra® was and is safe and effective when used in accordance
 23 with its FDA-approved prescribing information. Defendants state that the potential effects of
 24 Bextra® were and are adequately described in its FDA-approved prescribing information,
 25 which was at all times adequate and comported with applicable standards of care and law.
 26 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
 27 and deny the remaining allegations in this paragraph of the Complaint.

28 2. Defendants are without knowledge or information sufficient to form a belief as to the

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1 truth of the allegations regarding Plaintiff's age and citizenship, and, therefore, deny the same.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 3. Defendants admit that Pfizer is a Delaware corporation with its principal place of
4 business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as
5 the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer.
6 Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted
7 Bextra® in the United States, including Puerto Rico, to be prescribed by healthcare providers
8 who are by law authorized to prescribe drugs in accordance with their approval by the FDA.
9 Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and
10 ambiguous. Defendants are without knowledge or information to form a belief as to the truth of
11 such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in
12 this paragraph of the Complaint.

13 4. Defendants admit that Searle is a Delaware limited liability company with its principal
14 place of business in Illinois. Defendants admit that, during certain periods of time, Bextra®
15 was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted
16 and distributed Bextra® in the United States to be prescribed by healthcare providers who are
17 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
18 deny the remaining allegations in this paragraph of the Complaint.

19 5. Defendants admit that Pharmacia is a Delaware corporation with its principal place of
20 business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia
21 marketed and co-promoted Bextra® in the United States, including Puerto Rico, to be
22 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
23 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding
24 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
25 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
26 Defendants deny the remaining allegations in this Paragraph of the Complaint.

27 **Response to Allegations Regarding Jurisdiction and Venue**

28 6. Defendants are without knowledge or information to form a belief as to the truth of the

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1 allegations in this paragraph of the Complaint regarding the amount in controversy, and,
2 therefore, deny that the same. However, Defendants admit that Plaintiff claims that the amount
3 in controversy exceeds \$75,000, exclusive of interests and costs.

4 7. Defendants are without knowledge or information sufficient to form a belief as to the
5 truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and
6 the amount in controversy, and, therefore, deny the same. However, Defendants admit that
7 Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000,
8 exclusive of interests and costs.

9 8. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding the judicial district in
11 which the asserted claims allegedly arose, and, therefore, deny the same. Defendants deny
12 committing a tort in the State of Florida or the State of California and deny the remaining
13 allegations in this paragraph of the Complaint.

14 9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
15 and co-promoted Bextra® in the United States, including Puerto Rico, to be prescribed by
16 healthcare providers who are by law authorized to prescribe drugs in accordance with their
17 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
18 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
19 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
20 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
21 admit that they provided FDA-approved prescribing information regarding Bextra®.
22 Defendants admit that they do business in the State of Puerto Rico. Defendants state that
23 Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous.
24 Defendants are without knowledge or information to form a belief as to the truth of such
25 allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
26 remaining allegations in this paragraph of the Complaint.

27 **Response to Allegations Regarding Interdistrict Assignment**

28 10. Defendants state that this paragraph of the Complaint contains legal contentions to

1 which no response is required. To the extent that a response is deemed required, Defendants
2 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
3 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
4 Panel on Multidistrict Litigation on September 6, 2005.

5 **Response to Factual Allegations**

6 11. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
8 Defendants deny the remaining allegations in this paragraph of the Complaint.

9 12. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used
11 Bextra® and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury
12 or damage, and deny the remaining allegations in this paragraph of the Complaint.

13 13. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations regarding Plaintiff's medical condition and whether Plaintiff used
15 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that
16 Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph
17 of the Complaint.

18 14. Defendants admit that Bextra® was expected to reach consumers without substantial
19 change from the time of sale. Defendants are without knowledge or information sufficient to
20 form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and,
21 therefore, deny the same. Defendants deny the remaining allegations this paragraph of the
22 Complaint.

23 15. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants are without knowledge or information sufficient to form a belief as to the truth of
28 the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.

1 Defendants deny remaining the allegations in this paragraph of the Complaint.

2 16. Plaintiff's Complaint omits Paragraph Number 16.

3 17. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-
4 steroidal anti-inflammatory drugs ("NSAIDS"). Defendants state that Bextra® was and is safe
5 and effective when used in accordance with its FDA-approved prescribing information.
6 Defendants state that the potential effects of Bextra® were and are adequately described in its
7 FDA-approved prescribing information, which was at all times adequate and comported with
8 applicable standards of care and law. Defendants deny the remaining allegations in this
9 paragraph of the Complaint.

10 18. The allegations in this paragraph of the Complaint are not directed toward Defendants
11 and, therefore, no response is required. To the extent a response is deemed required,
12 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
13 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
14 form a belief as to the truth of such allegations and, therefore, deny the same.

15 19. The allegations in this paragraph of the Complaint are not directed toward Defendants
16 and, therefore, no response is required. To the extent a response is deemed required,
17 Defendants state that Plaintiff fails to provide the proper context for the allegations in this
18 paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to
19 form a belief as to the truth of such allegations and, therefore, deny the same.

20 Answering the unnumbered paragraph following Paragraph 19 of the Complaint,
21 Defendants state that the allegations in this paragraph of the Complaint are not directed toward
22 Defendants and, therefore, no response is required. To the extent a response is deemed
23 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
24 this paragraph of the Complaint. Defendants therefore lack sufficient information or
25 knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

26 20. Plaintiff fails to provide the proper context for the allegations in this paragraph of the
27 Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth
28 of such allegations and, therefore, deny the same.

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21. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

22. Plaintiff does not allege having used Celebrex® in this Complaint. Nevertheless, Defendants admit that Celebrex® was launched in the United States in February 1999. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

23. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in

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1 this paragraph of the Complaint.

2 24. Defendants admit that Bextra® was approved by the FDA on November 16, 2001.
3 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
4 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
5 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
6 allegations in this paragraph of the Complaint.

7 25. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
8 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
9 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny
10 the remaining allegations in this paragraph of the Complaint.

11 26. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
12 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
13 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
14 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
15 prescribing information. Defendants state that the potential effects of Bextra® were and are
16 adequately described in its FDA-approved prescribing information, which at all times was
17 adequate and comported with applicable standards of care and law. Defendants deny the
18 remaining allegations in this paragraph of the Complaint.

19 27. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which at all times was adequate and comported with applicable standards of care and law.
23 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
24 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
25 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
26 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
27 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
28 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance

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1 with their approval by the FDA. Defendants state that Plaintiff's allegations regarding
2 "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or
3 information to form a belief as to the truth of such allegations, and, therefore, deny the same.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 28. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which at all times was adequate and comported with applicable standards of care and law.
10 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
11 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
12 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
13 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
14 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
15 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
16 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
17 remaining allegations in this paragraph of the Complaint.

18 29. Defendants state that the referenced article speaks for itself and respectfully refer the
19 Court to the article for its actual language and text. Any attempt to characterize the article is
20 denied. Defendants state that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
22 this paragraph of the Complaint.

23 30. The allegations in this paragraph of the Complaint are not directed towards Defendants
24 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
25 state that the referenced article speaks for itself and respectfully refer the Court to the article for
26 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
27 the remaining allegations in this paragraph of the Complaint.

28 31. Defendants admit that the New Drug Application for Bextra® was filed with the FDA

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1 on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November
2 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this
3 paragraph of the Complaint.

4 32. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which at all times was adequate and comported with applicable standards of care and law.
8 Defendants deny the allegations in this paragraph of the Complaint.

9 33. Defendants state that the referenced FDA Talk Paper for Bextra® speaks for itself and
10 respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to
11 characterize the Talk Paper is denied. Defendants deny the remaining allegations in this
12 paragraph of the Complaint.

13 34. Defendants state that the referenced article speaks for itself and respectfully refer the
14 Court to the article for its actual language and text. Any attempt to characterize the article is
15 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

16 35. Plaintiff fails to provide the proper context for the allegations concerning the “post-drug
17 approval meta-analysis study” in this paragraph of the Complaint. Defendants are without
18 sufficient information to confirm or deny such allegations and, therefore, deny the same.
19 Defendants state that the referenced study speaks for itself and respectfully refer the Court to
20 the study for its actual language and text. Any attempt to characterize the study is denied.
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 36. The allegations in this paragraph of the Complaint are not directed towards Defendants
23 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
24 state that the referenced article speaks for itself and respectfully refer the Court to the article for
25 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
26 the remaining allegations in this paragraph of the Complaint.

27 37. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and

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1 deny the remaining allegations in this paragraph of the Complaint.

2 38. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
3 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
4 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
5 Defendants deny the remaining allegations in this paragraph of the Complaint.

6 39. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself
7 and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language
8 and text. Any attempt to characterize the Alert for Healthcare Professionals is denied.
9 Defendants deny the remaining allegations in this paragraph of the Complaint.

10 40. Defendants state that the referenced article speaks for itself and respectfully refer the
11 Court to the article for its actual language and text. Any attempt to characterize the article is
12 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

13 41. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
15 this paragraph of the Complaint.

16 42. Defendants state that the referenced article speaks for itself and respectfully refer the
17 Court to the article for its actual language and text. Any attempt to characterize the article is
18 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

19 43. Defendants state that the referenced article speaks for itself and respectfully refer the
20 Court to the article for its actual language and text. Any attempt to characterize the article is
21 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

22 44. Defendants state that the referenced articles speak for themselves and respectfully refer
23 the Court to the articles for their actual language and text. Any attempt to characterize the
24 articles is denied. Defendants deny the remaining allegations in this paragraph of the
25 Complaint.

26 45. Defendants state that the referenced article speaks for itself and respectfully refer the
27 Court to the article for its actual language and text. Any attempt to characterize the article is
28 denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 46. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants deny the allegations in this
3 paragraph of the Complaint.

4 47. Defendants state that the referenced article speaks for itself and respectfully refer the
5 Court to the article for its actual language and text. Any attempt to characterize the article is
6 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
7 paragraph of the Complaint.

8 48. The allegations in this paragraph of the Complaint are not directed towards Defendants
9 and, therefore, no response is necessary. Should a response be deemed necessary, Defendants
10 state that the referenced article speaks for itself and respectfully refer the Court to the article for
11 its actual language and text. Any attempt to characterize the article is denied. Defendants deny
12 the remaining allegations in this paragraph of the Complaint.

13 49. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny the allegations in this paragraph of the Complaint.

18 50. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
23 allegations in this paragraph of the Complaint.

24 51. Defendants state that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendants state that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of

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1 the Complaint.

2 52. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
3 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
4 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
5 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
6 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
7 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
8 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
9 effective when used in accordance with its FDA-approved prescribing information. Defendants
10 state that the potential effects of Bextra® were and are adequately described in its FDA-
11 approved prescribing information, which was at all times adequate and comported with
12 applicable standards of care and law. Defendants are without knowledge or information
13 sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used
14 Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct and deny the
15 allegations in this paragraph of the Complaint.

16 53. The allegations in this paragraph of the Complaint regarding Vioxx® are not directed
17 toward Defendants and, therefore, no response is required. To the extent a response is deemed
18 required, Defendants state that Plaintiff fails to provide the proper context for the allegations in
19 this paragraph of the Complaint regarding Vioxx®. Defendants therefore lack sufficient
20 information or knowledge to form a belief as to the truth of such allegations and, therefore,
21 deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in
22 this paragraph of the Complaint.

23 54. Defendants state that the referenced article speaks for itself and respectfully refer the
24 Court to the article for its actual language and text. Any attempt to characterize the article is
25 denied. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 55. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
28 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are

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1 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
2 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
3 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
4 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
5 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
6 effective when used in accordance with its FDA-approved prescribing information. Defendants
7 state that the potential effects of Bextra® were and are adequately described in its FDA-
8 approved prescribing information, which was at all times adequate and comported with
9 applicable standards of care and law. Defendants deny the remaining allegations in this
10 paragraph of the Complaint.

11 56. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and
16 deny the remaining allegations in this paragraph of the Complaint.

17 57. Defendants admit that the FDA Division of Drug Marketing, Advertising, and
18 Communications (“DDMAC”) sent a letter to Pfizer dated January 10, 2005. Defendants state
19 that the referenced letter speaks for itself and respectfully refer the Court to the letter for its
20 actual language and text. Any attempt to characterize the letter is denied. Defendants admit
21 that the DDMAC sent a letter to Searle dated October 6, 1999. Defendants state that the
22 referenced letter speaks for itself and respectfully refer the Court to the letter for its actual
23 language and text. Any attempt to characterize the letter is denied. Defendants state that the
24 transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and
25 respectfully refer the Court to the transcripts for their actual language and text. Any attempt to
26 characterize the transcripts is denied. Defendants state that the referenced study speaks for
27 itself and respectfully refer the Court to the article for its actual language and text. Any attempt
28 to characterize the article is denied. Defendants deny the remaining allegations in this

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1 paragraph of the Complaint.

2 58. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra®
3 is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
4 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
5 that the referenced press release speaks for itself and respectfully refer the Court to the press
6 release for its actual language and text. Any attempt to characterize the press release is denied.
7 Defendants state that the referenced article speaks for itself and respectfully refer the Court to
8 the article for its actual language and text. Any attempt to characterize the article is denied.
9 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
10 the Complaint.

11 59. Defendants state that the referenced press release speaks for itself and respectfully refer
12 the Court to the press release for its actual language and text. Any attempt to characterize the
13 press release is denied. Defendants deny any wrongful conduct and deny the remaining
14 allegations in this paragraph of the Complaint.

15 60. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
16 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
17 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
18 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
19 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
20 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
21 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 state that the potential effects of Bextra® were and are adequately described in its FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendants admit, as indicated in the package insert
26 approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms
27 of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary
28 dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

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61. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

62. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

63. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

64. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
3 the Complaint.

4 65. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 66. Defendants deny the allegations in this paragraph of the Complaint.

11 67. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
12 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
13 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
16 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Bextra® were and are adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
22 remaining allegations in this paragraph of the Complaint.

23 68. Defendants are without knowledge or information sufficient to form a belief as to the
24 truth of the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the
25 same. Defendants state that the referenced press releases speak for themselves and respectfully
26 refer the Court to the press releases for their actual language and text. Any attempt to
27 characterize the press releases is denied. Defendants state that Bextra® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 state that the potential effects of Bextra® were and are adequately described in its FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
4 remaining allegations in this paragraph of the Complaint.

5 69. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations regarding and whether Plaintiff used Bextra® and, therefore, deny the
7 same. Defendants state that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendants state that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
12 and deny the remaining allegations in this paragraph of the Complaint.

13 70. Defendants state that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendants state that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
18 allegations in this paragraph of the Complaint.

19 71. Defendants state that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendants state that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 72. Defendants deny any wrongful conduct and deny the remaining allegations in this
26 paragraph of the Complaint.

27 73. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-
4 promoted Bextra® in the United States to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
6 that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which
7 developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be
8 prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance
9 with their approval by the FDA. Defendants deny any wrongful conduct and deny the
10 remaining allegations in this paragraph of the Complaint.

11 74. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
12 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
13 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
16 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 **Response to First Cause of Action: Negligence**

20 75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
21 Complaint as if fully set forth herein.

22 76. Defendants state that this paragraph of the Complaint contains legal contentions to
23 which no response is deemed required. To the extent a response is deemed required,
24 Defendants admit that they had duties as are imposed by law but deny having breached such
25 duties. Defendants state that the potential effects of Bextra® were and are adequately described
26 in its FDA-approved prescribing information, which was at all times adequate and comported
27 with applicable standards of care and law. Defendants state that Bextra® was and is safe and
28 effective when used in accordance with its FDA-approved prescribing information. Defendants

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1 deny the remaining allegations in this paragraph of the Complaint.

2 77. Defendants state that this paragraph of the Complaint contains legal contentions to
3 which no response is deemed required. To the extent a response is deemed required,
4 Defendants admit that they had duties as are imposed by law but deny having breached such
5 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendants deny the remaining allegations in
7 this paragraph of the Complaint.

8 78. Defendants state that this paragraph of the Complaint contains legal contentions to
9 which no response is required. To the extent that a response is deemed required, Defendants
10 admit that they had duties as are imposed by law but deny having breached such duties.
11 Defendants state that Bextra® was and is safe and effective when used in accordance with its
12 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
13 were and are adequately described in its FDA-approved prescribing information, which was at
14 all times adequate and comported with applicable standards of care and law. Defendants deny
15 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint,
16 including all subparts.

17 79. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants are without knowledge or information sufficient to form a belief as to the truth of
22 the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
23 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
24 the Complaint.

25 80. Defendants state that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

84. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph Number 84 of the Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

85. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

86. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants admit that Bextra® was expected to reach consumers without substantial change in the condition from the time of sale. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their

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1 approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was
2 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
3 distributed Bextra® in the United States to be prescribed by healthcare providers who are by
4 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
5 deny the remaining allegations in this paragraph of the Complaint.

6 87. Defendants state that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendants state that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendants deny the allegations in this paragraph of the Complaint.

11 88. Defendants state that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendants state that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
16 allegations in this paragraph of the Complaint.

17 89. Defendants state that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants deny that Bextra® is defective or unreasonably dangerous, and deny the remaining
22 allegations in this paragraph of the Complaint.

23 90. Defendants state that this paragraph of the Complaint contains legal contentions to
24 which no response is required. To the extent that a response is deemed required, Defendants
25 are without knowledge or information sufficient to form a belief as to the truth of the
26 allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants
27 state that Bextra® was and is safe and effective when used in accordance with its FDA-
28 approved prescribing information. Defendants state that the potential effects of Bextra® were

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1 and are adequately described in its FDA-approved prescribing information, which was at all
2 times adequate and comported with applicable standards of care and law. Defendants deny that
3 Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
4 paragraph of the Complaint, including all subparts.

5 91. Defendants are without knowledge or information sufficient to form a belief as to the
6 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
7 Defendants state that Bextra® was and is safe and effective when used in accordance with its
8 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
9 were and are adequately described in its FDA-approved prescribing information, which was at
10 all times adequate and comported with applicable standards of care and law. Defendants deny
11 that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this
12 paragraph of the Complaint.

13 92. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
15 Defendants state that Bextra® was and is safe and effective when used in accordance with its
16 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
17 were and are adequately described in its FDA-approved prescribing information, which was at
18 all times adequate and comported with applicable standards of care and law. Defendants deny
19 that Bextra® is defective and deny the remaining allegations in this paragraph of the Complaint.

20 93. Defendants state that this paragraph of the Complaint contains legal contentions to
21 which no response is deemed required. To the extent a response is deemed required,
22 Defendants deny the allegations in this paragraph of the Complaint.

23 94. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra®
28 caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the

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1 Complaint.

2 95. Defendants state that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining
7 allegations in this paragraph of the Complaint.

8 96. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants state that Bextra® was and is safe and effective when used in accordance with its
11 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
12 were and are adequately described in its FDA-approved prescribing information, which was at
13 all times adequate and comported with applicable standards of care and law. Defendants admit
14 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra®
15 in the United States to be prescribed by healthcare providers who are by law authorized to
16 prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during
17 certain periods of time, Bextra® was manufactured and packaged for Searle, which developed,
18 tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by
19 healthcare providers who are by law authorized to prescribe drugs in accordance with their
20 approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is defective,
21 deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this
22 paragraph of the Complaint.

23 97. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny the remaining allegations in this paragraph of the Complaint.

28 98. Defendants state that this paragraph of the Complaint contains legal contentions to

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1 which no response is deemed required. To the extent a response is deemed required,
2 Defendants admit that they had duties as are imposed by law but deny having breached such
3 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Bextra® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny the remaining allegations in this paragraph of the Complaint.

8 99. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants state that Bextra® was and is safe and effective when used in accordance with its
11 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
12 were and are adequately described in its FDA-approved prescribing information, which was at
13 all times adequate and comported with applicable standards of care and law. Defendants deny
14 the remaining allegations in this paragraph of the Complaint.

15 100. Defendants state that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendants deny any wrongful conduct and
17 deny the remaining allegations in this paragraph of the Complaint.

18 101. Defendants state that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendants state that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
23 the Complaint.

24 102. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
25 damage, and deny the remaining allegations in this paragraph of the Complaint.

26 103. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
27 damage, and deny the remaining allegations in this paragraph of the Complaint.

28 Answering the unnumbered paragraph following Paragraph Number 103 of the

1 Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury
2 or damage, and deny the remaining allegations in this paragraph of the Complaint.

3 **Response to Third Cause of Action: Breach of Express Warranty**

4 104. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
5 Complaint as if fully set forth herein.

6 105. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
8 Defendants state that Bextra® was and is safe and effective when used in accordance with its
9 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
10 were and are adequately described in its FDA-approved prescribing information, which was at
11 all times adequate and comported with applicable standards of care and law. Defendants admit
12 that they provided FDA-approved prescribing information regarding Bextra®. Defendants
13 deny the remaining allegations in this paragraph of the Complaint.

14 106. Defendants are without knowledge or information sufficient to form a belief as to the
15 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
16 Defendants state that Bextra® was and is safe and effective when used in accordance with its
17 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
18 were and are adequately described in its FDA-approved prescribing information, which was at
19 all times adequate and comported with applicable standards of care and law. Defendants admit
20 that they provided FDA-approved prescribing information regarding Bextra®. Defendants
21 deny the remaining allegations in this paragraph of the Complaint, including all subparts.

22 107. Defendants deny the allegations in this paragraph of the Complaint.

23 108. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants admit that they provided FDA-approved prescribing information regarding
28 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

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1 109. Defendants state that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendants state that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendants admit that they provided FDA-approved prescribing information regarding
6 Bextra®. Defendants deny any wrongful conduct the remaining allegations in this paragraph of
7 the Complaint.

8 110. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
10 Defendants admit that they provided FDA-approved prescribing information regarding
11 Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

12 111. Defendants state that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
17 the Complaint.

18 112. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
19 damage, and deny the remaining allegations in this paragraph of the Complaint.

20 113. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
21 damage, and deny the remaining allegations in this paragraph of the Complaint.

22 Answering the unnumbered paragraph following Paragraph Number 113 of the
23 Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury
24 or damage, and deny the remaining allegations in this paragraph of the Complaint.

25 **Response to Fourth Cause of Action: Breach of Implied Warranty**

26 114. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
27 Complaint as if fully set forth herein.

28 115. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed

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1 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
2 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
3 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
4 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
5 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
6 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
7 paragraph of the Complaint.

8 116. Defendants admit that they provided FDA-approved prescribing information regarding
9 Bextra®. Defendants admit, as indicated in the package insert approved by the FDA, that
10 Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult
11 rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state
12 that Bextra® was and is safe and effective when used in accordance with its FDA-approved
13 prescribing information. Defendants deny the remaining allegations in this paragraph of the
14 Complaint.

15 117. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
17 Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is
18 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
19 arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining
20 allegations in this paragraph of the Complaint.

21 118. Defendants are without knowledge or information sufficient to form a belief as to the
22 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
23 Defendants state that Bextra® was and is safe and effective when used in accordance with its
24 FDA-approved prescribing information. Defendants deny the remaining allegations in this
25 paragraph of the Complaint.

26 119. Defendants are without knowledge or information sufficient to form a belief as to the
27 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
28 Defendants state that Bextra® was expected to reach consumers without substantial change in

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1 the condition from the time of sale. Defendants deny the remaining allegations in this
2 paragraph of the Complaint.

3 120. Defendants are without knowledge or information sufficient to form a belief as to the
4 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
5 Defendants state that Bextra® was and is safe and effective when used in accordance with its
6 FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the
7 remaining allegations in this paragraph of the Complaint.

8 121. Defendants state that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendants state that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 122. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
15 damage, and deny the remaining allegations in this paragraph of the Complaint.

16 123. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
17 damage, and deny the remaining allegations in this paragraph of the Complaint.

18 Answering the unnumbered paragraph following Paragraph Number 123 of the
19 Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury
20 or damage, and deny the remaining allegations in this paragraph of the Complaint.

21 **Response to Fifth Cause of Action: Fraudulent Misrepresentation & Concealment**

22 124. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
23 Complaint as if fully set forth herein.

24 125. Defendants state that this paragraph of the Complaint contains legal contentions to
25 which no response is deemed required. To the extent a response is deemed required,
26 Defendants admit that they had duties as are imposed by law but deny having breached such
27 duties. Defendants state that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendants state that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendants deny the remaining allegations in this paragraph of the Complaint.

4 126. Defendants state that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint, including all subparts.

10 127. Defendants state that Bextra® was and is safe and effective when used in accordance
11 with its FDA-approved prescribing information. Defendants state that the potential effects of
12 Bextra® were and are adequately described in its FDA-approved prescribing information,
13 which was at all times adequate and comported with applicable standards of care and law.
14 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
15 the Complaint.

16 128. Defendants state that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendants state that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably
21 dangerous, and deny the remaining allegations in this paragraph of the Complaint.

22 129. Defendants state that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendants state that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
27 the Complaint.

28 130. Defendants deny any wrongful conduct and deny the remaining allegations in this

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1 paragraph of the Complaint.

2 131. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
4 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
5 the Complaint.

6 132. Defendants are without knowledge or information sufficient to form a belief as to the
7 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
8 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
9 the Complaint.

10 133. Defendants are without knowledge or information sufficient to form a belief as to the
11 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
12 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
13 the Complaint.

14 134. Defendants deny any wrongful conduct and deny the remaining allegations in this
15 paragraph of the Complaint.

16 135. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
18 Defendants state that Bextra® was and is safe and effective when used in accordance with its
19 FDA-approved prescribing information. Defendants state that the potential effects of Bextra®
20 were and are adequately described in its FDA-approved prescribing information, which was at
21 all times adequate and comported with applicable standards of care and law. Defendants deny
22 any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23 136. Defendants state that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of
28 the Complaint.

1 137. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
2 damage, and deny the remaining allegations in this paragraph of the Complaint.

3 138. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
4 damage, and deny the remaining allegations in this paragraph of the Complaint.

5 Answering the unnumbered paragraph following Paragraph Number 138 of the
6 Complaint, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury
7 or damage, and deny the remaining allegations in this paragraph of the Complaint.

8 **Response to Sixth Cause of Action: Unjust Enrichment**

9 139. Defendants incorporate by reference their responses to each paragraph of Plaintiff's
10 Complaint as if fully set forth herein.

11 140. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
12 and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are
13 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
14 admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle,
15 which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to
16 be prescribed by healthcare providers who are by law authorized to prescribe drugs in
17 accordance with their approval by the FDA. Defendants deny the remaining allegations in this
18 paragraph of the Complaint.

19 141. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
21 Defendants deny the remaining allegations in this paragraph of the Complaint.

22 142. Defendants are without knowledge or information sufficient to form a belief as to the
23 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
24 Defendants deny the remaining allegations in this paragraph of the Complaint.

25 143. Defendants are without knowledge or information sufficient to form a belief as to the
26 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
27 Defendants state that Bextra® was and is safe and effective when used in accordance with its
28 FDA-approved prescribing information. Defendants deny the remaining allegations in this

1 paragraph of the Complaint.

2 144. Defendants are without knowledge or information sufficient to form a belief as to the
3 truth of the allegations regarding whether Plaintiff used Bextra® and, therefore, deny the same.
4 Defendants deny the remaining allegations in this paragraph of the Complaint.

5 Answering the unnumbered paragraph of the Complaint following Paragraph Number
6 144, Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or
7 damage, and deny the remaining allegations in this paragraph of the Complaint.

8 **Response to Prayer for Relief**

9 Answering the unnumbered paragraph of the Complaint headed “Prayer for Relief,”
10 Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage,
11 and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

12 **III.**

13 **GENERAL DENIAL**

14 Defendants deny all allegations and/or legal conclusions set forth in Plaintiff’s
15 Complaint that have not been previously admitted, denied, or explained.

16 **IV.**

17 **AFFIRMATIVE DEFENSES**

18 Defendants reserve the right to rely upon any of the following or additional defenses to
19 claims asserted by Plaintiff to the extent that such defenses are supported by information
20 developed through discovery or evidence at trial. Defendants affirmatively show that:

21 **First Defense**

22 1. The Complaint fails to state a claim upon which relief can be granted.

23 **Second Defense**

24 2. Bextra® is a prescription medical product. The federal government has preempted the
25 field of law applicable to the labeling and warning of prescription medical products.
26 Defendants’ labeling and warning of Bextra® was at all times in compliance with applicable
27 federal law. Plaintiff’s causes of action against Defendants, therefore, fail to state a claim upon
28

1 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
2 and violate the Supremacy Clause of the United States Constitution.

3 **Third Defense**

4 3. At all relevant times, Defendants provided proper warnings, information, and
5 instructions for the drug in accordance with generally recognized and prevailing standards in
6 existence at the time.

7 **Fourth Defense**

8 4. At all relevant times, Defendants' warnings and instructions with respect to the use of
9 Bextra® conformed to the generally recognized, reasonably available, and reliable state of
10 knowledge at the time the drug was manufactured, marketed, and distributed.

11 **Fifth Defense**

12 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the
13 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendants.

14 **Sixth Defense**

15 6. Plaintiff's action is barred by the statute of repose.

16 **Seventh Defense**

17 7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily
18 negligent, actively negligent or otherwise failed to mitigate Plaintiff's damages, and any
19 recovery by Plaintiff should be diminished accordingly.

20 **Eighth Defense**

21 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
22 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
23 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
24 liable in any way.

25 **Ninth Defense**

26 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
27 intervening causes for which Defendants cannot be liable.

28

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Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff’s treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff’s causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff’s alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendants and any liability of

Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution, and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. Defendants affirmatively aver that the imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of Florida and California, and would additionally violate Defendants' rights to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth

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Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitutions of the States of Florida and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

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Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured, and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act

1 (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff’s
2 claims conflict with the FDCA, with the regulations promulgated by FDA to implement the
3 FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations,
4 and with the specific determinations by FDA specifying the language that should be used in the
5 labeling accompanying Bextra®. Accordingly, Plaintiff’s claims are preempted by the
6 Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the
7 United States.

8 **Fifty-fourth Defense**

9 54. Plaintiff’s misrepresentation allegations are not stated with the degree of particularity
10 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

11 **Fifty-fifth Defense**

12 55. Defendants state on information and belief that the Complaint and each purported cause
13 of action contained therein is barred by the statutes of limitations contained in California Code
14 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation
15 as may apply.

16 **Fifty-sixth Defense**

17 56. Defendants state on information and belief that any injuries, losses, or damages suffered
18 by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable
19 conduct of persons or entities other than Defendants. Therefore, Plaintiff’s recovery against
20 Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

21 **Fifty-seventh Defense**

22 57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of
23 Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil
24 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
25 damages is also barred under California Civil Code § 3294(b).

26 **Fifty-eighth Defense**

27 58. Plaintiff’s fraud-based claims, if any, are not stated with particularity as required by
28 Rule 1.120 of the Florida Rules of Civil Procedure.

Fifty-ninth Defense

59. Plaintiff's claims are barred because Bextra® was designed, manufactured, and marketed in accordance with the state of the art at the time of manufacture per § 768.1257, Florida Statutes.

Sixtieth Defense

60. Bextra® is not defective or unreasonably dangerous, and Defendants are not liable because, at the time of sale or distribution of the Bextra® alleged to have been used by Plaintiff, Defendants had complied with applicable regulations of the federal Food & Drug Administration and are entitled to application of § 768.1256, Florida Statutes.

Sixty-first Defense

61. Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiff's recovery. Thus, Defendants are entitled to have their liability to the Plaintiff, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of § 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to §§ 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262 (Fla. 1996).

Sixty-second Defense

62. Plaintiff fails to state a claim for violation of The Florida Deceptive and Unfair Trade Practices Act ("FDUTPA").

Sixty-third Defense

63. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiff's FDUTPA claim is improper and should be dismissed.

Sixty-fourth Defense

64. The acts or practices of which Plaintiff complains were and are required or specifically permitted by federal or state law. Therefore, Plaintiff's FDUTPA claim is barred, fails to state a claim, and should be dismissed with prejudice.

Sixty-fifth Defense

65. Plaintiff lacks standing because Defendants did not engage in deceptive conduct with regard to Plaintiff or otherwise.

Sixty-sixth Defense

66. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

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1 October 5, 2007

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JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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